

REMARKS/ARGUMENTS

Applicants have received and carefully reviewed the Final Office Action mailed July 12, 2010. Claims 1, 3-10, 12-21, and 23-31 are pending and have been rejected. Applicants respectfully traverse all adverse assertions and rejections presented in the Final Office Action. With this amendment, claims 1, 14, 23, and 27 have been amended to correct a typographical error. No new matter has been added and no substantive claim amendments are presented herein. Applicants submit that the claim amendments create no additional search burden, and that the Examiner has already interpreted the claims in the way they are being amended to read. Therefore, entrance and favorable consideration of the above amendments and the following remarks are respectfully requested.

As an informal matter, Applicants note that the body of each rejection refers to the Fischell et al. reference, which is no longer being applied as prior art against the pending application. Correction in any future Office Action is respectfully requested.

Claim Amendments

Independent claims 1, 14, 23, and 27 have been amended to correct a typographical error. In particular, the annular space between the inner tube and the outer tube is not in fluid communication with the lumen of the inner tube and from the exterior of the balloon. In the Final Office Action, the Examiner correctly interpreted the claims as they are being amended to recite.

Claim Rejections – 35 USC § 103

Claims 1, 4-7, 9, 10, 14-16, 18, 19, and 23-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski (U.S. Patent No. 6,579,305) in view of Lau et al. (U.S. Patent No. 5,421,955) and further in view of Stack et al. (U.S. Patent No. 6,264,683). After careful review, Applicants must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

With respect to independent claims 1, 14, and 23, the Final Office Action acknowledges that Lashinski does not disclose or suggest all of the structural limitations of the claims. Lau et al. are introduced as providing an annular space is not in fluid communication with the lumen of the inner tube and an exterior of the balloon, and Stack et al. are introduced as providing a distal tip with a proximal edge defining an edge diameter and a distal end of an outer tube defining a distal end diameter, where the distal end diameter and the edge diameter are equal to or greater than a maximum outer diameter of the stent in an unexpanded form.

Applicants submit that the asserted combination of references appears to be improper. With respect to Lau et al., Applicants note that Lashinski expressly discloses that controlled leakage of the temperature-controlled fluid from the balloon maintains the temperature of the fluid in the balloon (column 4, lines 55-60), and also Lashinski expressly states that “[t]he fluid is continually replenished through inflation lumen 25, thus maintaining the pressure and temperature of the fluid in balloon 27” (see column 5, lines 43-47). The closed system of Lau et al., which the Examiner has proposed to use to “simplify” the device of Lashinski, does not appear to permit the required replenishment. Without the replenishment disclosed by Lashinski, it appears that the fluid inside the balloon, which directly affects the expansion of the surrounding stent, would not be maintained at the desired temperature and pressure. As the balloon cools (the elevated temperature of the “warm” fluid in the balloon of Lau et al. would naturally and necessarily be reduced by the relatively cooler surrounding environment), fluid would have to be removed under vacuum, thereby reducing the pressure in the balloon, and then replaced with fluid at a higher temperature – effectively cycling the fluid temperature up and down rather than maintaining it; or additional fluid having an elevated temperature will need to be added to the fluid already in the balloon, thereby increasing the pressure within the balloon, and not “maintaining the pressure” as required by Lashinski. Neither method appears to meet the requirements of the system of Lashinski.

MPEP 2143.01 V states:

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

And MPEP 2143.01 VI states:

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)

Modification of Lashinski using the device of Lau et al. appears to impermissibly alter the principle of operation of Lashinski by removing the continuous replenishment of warm fluid which maintains the temperature and pressure within the balloon, rendering it unsuitable for its intended use. Therefore, the proposed modification in view of Lau et al. appears to be improper.

With respect to Stack et al. and in contrast to the assertions of the Examiner, Stack et al. do not appear to disclose a stent delivery device with an inner tube having a distal tip with a proximal edge diameter and an outer tube defining a distal end diameter. Instead, Stack et al. appear to disclose a single catheter 10 comprising shaft 12 having two side-by-side lumens, inflation lumen 15 which extends to a proximal end of a balloon, and guidewire lumen 16 which extends through the balloon. However, one of ordinary skill in the art would not consider the side-by-side construction of Stack et al. as comprising “inner” and “outer” tubes, the inner tube being disposed within the outer tube, as required by the claims. Furthermore, Stack et al. do not appear to disclose two tubes arranged concentrically or otherwise so as to form an annular space between them, as required by the claims. Accordingly, one of ordinary skill in the art would not look to Stack et al. to modify the device disclosed by Lashinski.

Additionally, Applicants note that distal stent bumper 20 of Stack et al. appears to have an exaggerated protrusion to one side of inflation lumen 16, so as to provide concentric mounting of the balloon and stent with respect to a central axis of shaft 12. The addition of stent bumper 20 to the generally concentric tubes of Lashinski would appear to create an undesirable protrusion to one side of the device, which may create interference or otherwise negatively affect the insertion or withdrawal of the device through narrowed vessels within the vasculature.

For at least these reasons, it appears that the combination of Stack et al. with Lashinski and/or Lau et al. appears to be improper.

Applicants submit that Lashinski, Lau et al., and Stack et al., alone or in combination, do not appear to properly disclose or suggest all of the elements of independent claims 1, 14, and 23, as is required to establish a *prima facie* rejection. Accordingly, independent claims 1, 14, and 23 are believed to be patentable over the cited references. Since claims 4-7, 9, 10, 15, 16, 18, 19, and 24-26 depend from independent claims 1, 14, and 23 and add additional elements thereto, these claims are also believed to be patentable over the cited references.

Additionally, Applicants respectfully point out that none of the cited references appear to disclose or suggest the inner tube comprises a distal radiopaque marker disposed immediately proximal to the distal tip and a proximal radiopaque marker immediately distal to the distal end of the outer tube, as required by dependent claim 10, in addition to the deficiencies noted above with respect to claim 1.

Applicants respectfully request that the rejection be withdrawn.

Claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. as applied to claim 1, and further in view of Klein (U.S. Patent No. 6,605,107). After careful review, Applicants must respectfully traverse this rejection.

As discussed above, independent claim 1 is believed to be patentable over Lashinski in view of Lau et al. and Stack et al. Klein does not appear to remedy the shortcomings of Lashinski, Lau et al., and Stack et al. with respect to claim 1. Accordingly, claim 1 is believed to be patentable over the cited combination. Since claim 8 depends therefrom and adds additional elements thereto, claim 8 is also believed to be patentable over the cited references. Withdrawal of the rejection is respectfully requested.

Claim 17 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. as applied to claim 16, and further in view of Rabkin et al. (U.S. Patent No. 6,676,692). Claim 21 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. as applied to claim 19, and further in view of Healey et al. (U.S. Patent No. 6,607,553).

After careful review, Applicants must respectfully traverse these rejections.

As discussed above, independent claim 14 is believed to be patentable over Lashinski in view of Lau et al. and Stack et al. Neither Rabkin et al. nor Healey et al. appear to remedy the shortcomings of Lashinski, Lau et al., and Stack et al. with respect to claim 14. Accordingly, claim 14 is believed to be patentable over the cited combinations. Since claims 17 and 21 depend therefrom and add additional elements thereto, claims 17 and 21 are also believed to be patentable over the cited references.

Additionally, to the extent that the combination of Lashinski and Lau et al. is even possible, the proposed modification in view of Rabkin et al. appears to be improper. The Examiner has proposed to modify Lashinski with the closed system of Lau et al. This is believed to be improper for at least the reasons discussed above. If however, for the sake of argument, the combination is assumed to be possible, Applicants note that Rabkin et al. require an inflow channel and port, and an outflow channel and port, in order to circulate cool fluid. Fluid cannot be circulated as required by Rabkin et al. (in order to maintain temperature preventing premature expansion of the stent to enable precise positioning as described at column 18, lines 15-29) in the closed system device produced by modifying the device of Lashinski with that disclosed by Lau et al.

Withdrawal of the rejections is respectfully requested.

Claims 3, 12, 13, 20, and 27-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. as applied to claims 1 and 14, and further in view of Kasprzyk et al. (U.S. Patent No. 5,035,694). After careful review, Applicants must respectfully traverse this rejection.

As discussed above, independent claims 1 and 14 are believed to be patentable over Lashinski, Lau et al., and Stack et al. Kasprzyk et al. do not appear to remedy the shortcomings of Lashinski, Lau et al., and Stack et al. with respect to claims 1 and 14. Therefore, claims 1 and 14 are believed to be patentable over the cited combination. Since claims 3, 12, 13, and 20 depend from independent claims 1 and 14 and add additional elements thereto, these claims are also believed to be patentable over the cited references.

For at least the reasons discussed above with respect to claims 1, 14, and 23,

Lashinski, Lau et al., and Stack et al. do not appear to properly disclose or suggest all of the elements of claim 27, which requires similar elements. Kasprzyk et al. do not appear to remedy the shortcomings of Lashinski, Lau et al., and Stack et al. discussed above with respect to claim 27. Therefore, independent claim 27 is believed to be patentable over the cited references. Since claims 28-29 depend therefrom and add additional elements thereto, these claims are also believed to be patentable over the cited references.

Additionally, the Examiner asserts that Kasprzyk et al. disclose “a coil heating element (50, 51) for supplying heat to the immediate area surrounding a balloon” (Final Office Action, page 8), and that it would be obvious to supply current to the heating element of Lashinski, Lau et al., and Stack et al., as taught by Kasprzyk et al. Applicants respectfully disagree.

Initially, Applicants note that elements 50 and 51 are not disclosed as “supplying heat” to any portion of the device of Kasprzyk et al., and certainly not to the immediate area surrounding a balloon, since these elements are disposed within the balloon. Instead, Kasprzyk et al. appear to expressly disclose that elements 50 and 51 direct “electrical power from a source (not shown) exterior to the catheter to the electrically conductive layer 52” (column 5 line 66 to column 6, line 1) on an inside surface of the balloon, where the electrically conductive layer 52 provides heating (and would thus be considered the heating element by one of ordinary skill in the art). Electrically conductive layer 52 is not a coil, as required by dependent claim 2. Electrically conductive layer 52 is not “positioned on the distal end of the inner tube” as required by independent claim 27.

Additionally, the asserted heating element of the device of Lashinski, Lau et al., and Stack et al., is the inflation fluid itself (see page 2 of Final Office Action). Kasprzyk et al. do not appear to disclose or suggest supplying electrical current to the inflation fluid. Kasprzyk et al. appear to teach away from such a configuration at column 4, lines 62-65, where Kasprzyk et al. expressly state the inner conductive surface “may be coated with a thin insulating layer (not shown) to prevent contact with the inflation medium” and that on an outer conductive surface “an insulating coating would be required...to minimize current flow into the surrounding tissue when the balloon is inflated and heated” (column 3, lines 38-42), thereby indicating that electrical current is only desired

within the thin conductive layer which provides resistive heating, and not within the inflation fluid or surrounding tissue. Substituting the heating element of Kasprzyk et al. for the heated fluid of Lashinski (as proposed on pages 7-8 of the Final Office Action) would appear to significantly alter the principle of operation of Lashinski et al., which relies upon a constantly replenishing fluid supply to maintain temperature and pressure within the balloon.

For at least these reasons, the rejection appears to be improper and withdrawal of the rejection is respectfully requested.

Claim 30 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. and Kasprzyk et al. as applied to claim 27, and further in view of Rabkin et al. Claim 31 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. and Kasprzyk et al. as applied to claim 27, and further in view of Healey et al. After careful review, Applicants must respectfully traverse this rejection.

As discussed above, independent claim 27 is believed to be patentable over Lashinski in view of Lau et al., Stack et al., and Kasprzyk et al. Neither Rabkin et al. nor Healey et al. appear to remedy the shortcomings of Lashinski, Lau et al., Stack et al., and Kasprzyk et al. with respect to claim 27. Accordingly, claim 27 is believed to be patentable over the cited combinations. Since claims 30 and 31 depend therefrom and add additional elements thereto, claims 30 and 31 are also believed to be patentable over the cited references.

Additionally, to the extent that the combination of Lashinski and Lau et al. is even possible, the proposed modification in view of Rabkin et al. appears to be improper. The Examiner has proposed to modify Lashinski with the closed system of Lau et al. This is believed to be improper for at least the reasons discussed above. If however, for the sake of argument, the combination is assumed to be possible, Applicants note that Rabkin et al. require an inflow channel and port, and an outflow channel and port, in order to circulate cool fluid. Fluid cannot be circulated as required by Rabkin et al. (in order to maintain temperature preventing premature expansion of the stent to enable precise positioning as described at column 18, lines 15-29) in the closed system device produced

by modifying the device of Lashinski with that disclosed by Lau et al.

Withdrawal of the rejections is respectfully requested.

Conclusion

In view of the foregoing, all pending claims are believed to be in condition for allowance. Further examination, reconsideration, and withdrawal of the rejections are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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